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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,697	09/15/2003	William J. Boyle	ACS 65470 (2309D)	9777

24201 7590 07/07/2005

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

88

Office Action Summary	Application No. 10/662,697	Applicant(s) BOYLE ET AL.	
	Examiner Sarah K. Webb	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 35-38, 45-48, and 54-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,569,184 to Huter. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application simply includes obvious limitations such as a control handle on the proximal end of the device and the inner catheter is flexible tubing. The patent and application claim the same inventions, including the recovery device, the apparatus including the recovery device and filter, and the method of retrieving the filter using the recovery device.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 3731

2. Claims 38 and 48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inner catheter being more flexible than the recovery sheath, does not reasonably provide enablement for the inner catheter having greater column strength than the recovery sheath. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 35-40, 42-50, and 52-67 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,171,327 to Daniel et al.

Daniels illustrates a catheter system in Figures 20-23 that is designed for recovery of an embolic filter (21) that is disposed on a guide wire (26). The retrieval device includes an inner catheter (172 in Figure 20 or 372 in Figure 23) that extends distally beyond a recovery sheath (151). Claims 36, 46, 56, 57 are significantly broad enough to encompass any length of either catheter. The recovery sheath (151) tracks over the distal portion of the inner catheter to retrieve the filter, as shown in Figure 19. Daniels explains that the distal portion of the inner catheter is made of flexible material (column 8, lines 61-67). As evidenced by the fact that the recovery sheath

Art Unit: 3731

(151) is capable of deforming the distal end (180,280) of the inner catheter when pushed distally to retrieve the filter, the distal portion of the inner catheter is more flexible than the recovery sheath (151). Each catheter has a control handle attached to its proximal end, and the handles are illustrated in Figures 24-26. Control handle 702 is connected to the proximal end of the recovery sheath (151) and control handle 710 is connected to the proximal end of the inner catheter (372).

Inner catheter (372) can be locked onto the guide wire (26) by way of a threaded connection between the handle (710) and a locking mechanism that includes a guide wire clamp (720) and a collet (718). The recovery sheath control handle (702) is locked with the inner catheter control handle (710) by a stop (708) that prevents the handles (702,710) from becoming separated but allows the handles to slide relative to one another.

Regarding claims 36,46,56, and 57, the language "*may be up to*", "*may be up to approximately*", and "*may extend up to*" is significantly broad to include any length less than the stated dimension. Therefore, the Daniel device meets this limitation, since the recovery sheath is clearly shorter than the inner catheter.

Daniel discloses steps of using the device in column 10 that include advancing the inner catheter and recovery sheath over a guide wire, locking the inner catheter to the guide wire, advancing the recovery sheath over the filter to collapse it, and removing the entire system from the patient's body.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3731

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 41 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel in view of US Patent No. 5,201,757 to Heyn et al.

Daniel includes all the limitations of claims 41 and 51, except that the position of the handles is switched so that control handle of the recovery sheath is coaxially disposed within the lumen of the control handle of the inner catheter. Heyn discloses a device with control handles for sheaths that move relative to one another. Heyn teaches that the control handle (60) for the inner catheter (44) can be disposed within the control handle (56) of the outer sheath (20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to simply rearrange the control handles of Daniel so that the control handle of the inner catheter is disposed within the lumen of the recovery sheath handle, as Heyn teaches that this is an alternate way to configure control handles of relatively moving sheaths.

Response to Arguments

5. Applicant's arguments filed 6/17/05 have been fully considered but they are not persuasive. Applicant argues that the distal portion of the inner catheter in Figures 20-23 of the Daniels patent does not meet the limitation "*length of flexible tubing*" because it is bulky, short, and tapered. The distal portion (172,180) is part of the inner catheter, which is a flexible tube. Daniels explains that the entire inner catheter, including the distal tapered portion (180), is formed of flexible materials (column 8, lines 61-67). The distal portion has a length. Therefore, the distal portion,

Art Unit: 3731

regardless of its enlarged and tapered structure, meets the broad limitation "*length of flexible tubing.*" Further, claims 36,46,56, and 57 recite the phrases "*may be up to*", "*may be up to approximately*", and "*may extend up to*", which are significantly broad enough to encompass any relative lengths of the catheter tubes. Therefore, the Daniel device meets this limitation, since the recovery sheath is clearly shorter than the inner catheter.

Though the inner catheter and outer sheath are shown in a particular position in Figures 20-23, the proximal handles allow the tubes to be moved relative to one another. With the sheath retracted, the distal end of inner catheter would extend further past the distal end of the outer sheath.

The new limitation "*and the distal portion...of the body vessel*" does not provide any positive structural limitations that distinguish the prior art from the claimed invention. The new limitation is significantly broad enough to include any relative lengths of tubing.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 6,361,546 to Khosravi discloses a retrieval device for a filter (10) that is adapted to be advanced over a guide wire (68) in Figures 2G and 2H. The device (110) includes an inner catheter (114) with a proximal control handle (118) and a recovery sheath with a proximal control handle (128). The inner catheter is a flexible tube (column 6, line 56).

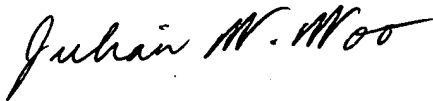
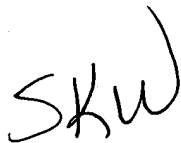
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
6/30/05



JULIAN W. WOO
PRIMARY EXAMINER